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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,921	03/27/2001	Ronald C. Lundquist	950.005US7	4952

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EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/818,921

Applicant(s)

LUNDQUIST ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 10-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-19, 21-25 and 27-32 is/are rejected.
- 7) ☒ Claim(s) 20 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 10-32 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

3. Claims 20 and 26 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 112

4. Claims 10-19, 21-25 and 27-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of bombardment of embryogenic maize cells for the production of transformed maize plants, does not reasonably provide enablement for a method of bombardment of any other regenerable maize tissues for the production of transformed maize plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 20 December 2003, as applied to claims 10-32. Applicant's arguments filed 29 March 2003 have been fully considered but they are not persuasive.

Applicant urges that the claims are not drawn to use of any cells, only intact regenerable cells, and the examples alone enable intact regenerable cells (response pg 5).

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This is not found persuasive because not all intact regenerable cells produce fertile plants. Rhodes et al (1988, BioTechnol. 6:56-60), cited in the prior Office action, teach that whole maize plants produced from protoplasts that had formed embryogenic callus were sterile (paragraph spanning pg 58-59).

Applicant urges that as long as the specification discloses making the invention in a reasonable correlation to the scope, the enablement requirement is satisfied (response pg 6).

This is not found persuasive because not all intact regenerable cells produce fertile plants. Thus the invention is not enabled within the full scope of the claims.

Applicant urges that claims exclude non-regenerable cells and that Green et al shows a high level of skill in the art (response pg 6-7).

This is not found persuasive because made in the action that any intact regenerable maize cells are inoperable, as discussed above.

Applicant urges that Green et al only establishes that embryogenic maize callus has advantages and that no suggestion is made in the action that any intact regenerable maize cells are inoperable (response pg 7).

This is not found persuasive because Rhodes et al teach that whole maize plants produced from protoplasts that had formed embryogenic callus were sterile (paragraph spanning pg 58-59). Thus, there was a suggestion made in the action that an intact regenerable maize cell was inoperable.

5. Claims 10-19, 21-25 and 27-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that

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Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is modified from the rejection set forth in the Office action mailed 20 December 2003, as applied to claims 10-32, due to Applicant's amendment of the claims. Applicant's arguments filed 39 March 2003 have been fully considered but they are not persuasive.

Claim 10 is indefinite because in step (ii) cells comprising the preselected DNA sequence are identified, while in step (iii) the DNA that comprises the preselected DNA sequence is expressed. The DNA that comprises the preselected DNA sequence cannot be expressed unless cells comprising it are identified in step (ii).

Applicant urges that the claim has been amended (response pg 8).

This is not found persuasive because step (ii) cells comprising only the preselected DNA sequence are identified, while in step (iii) the DNA that comprises the preselected DNA sequence is expressed. It is suggested that either --said DNA comprising-- be inserted before "said" in line 7 or "said DNA comprising" be deleted in line 8.

Claim 25 lacks antecedent basis for the limitation "the DNA encoding said endotoxin" in lines 2 and 1, respectively.

Applicant urges that claims 10 and 16-17, from which claim 25 depends, recite "preselected DNA sequence encoding a ... endotoxin", that claim 11, from which claim 25 also depends, is dependent upon claim 10; thus, there is antecedent basis (response pg 8-9).

This is not found persuasive because the claims recite "preselected DNA sequence encoding a ... endotoxin" (emphasis added), not "DNA encoding ...".

It is unclear in claim 21 if Applicant intended that the preselected DNA sequence comprises a selectable marker gene.

Applicant urges that claim 21 depends from claim 11, which recites “preselected DNA sequences further comprises a selectable marker gene” (response pg).

This is not found persuasive because claim 11 recites “preselected DNA sequences further comprises a selectable marker gene or a reporter gene”. It is not clear if the process in claim 21 is one in which the preselected DNA sequences further comprises a selectable marker gene, as opposed to a reporter gene, and that the selectable marker gene is one of those listed in the Markush group, or if the process of claim 21 is still one where the preselected DNA sequences may comprise a reporter gene.

Claims 28-29 lack antecedent basis for the limitation “the preselected DNA” in line 1

Applicant urges that the claims have been amended (response pg 10).

This is not found persuasive because the claims have not been amended to address this rejection.

Claim 29 lacks antecedent basis for the limitation “the DNA encoding the endotoxin” in lines 2-3.

Applicant urges that claim 10, from which claim 29 depends, recites “preselected DNA sequence encoding a ... endotoxin”; thus, there is antecedent basis (response pg 8-9).

This is not found persuasive because the claim recites “preselected DNA sequence encoding a ... endotoxin” (emphasis added), not “DNA encoding ...”.

It is unclear in claim 30 where the manopine synthase, nopaline synthase or octopine synthase promoter is located relative to the promoter recited in claim 19.

Applicant urges that they have amended claim 27 (response pg 10).

This is not found persuasive because this rejection is not drawn to claim 27.

It is unclear in claim 32 if any members of the population of plants comprise the preselected DNA sequence. It is also unclear if the parent plants are parent plants of the members of the population or if the members of the population are the parent plants.

Applicant did not address this rejection. It is noted that applicant's amendment to this claim does not obviate this rejection.

The following rejection is new, due to amendment of the claims:

Claim 25 is indefinite in its recitation of "DNA encoding ... *Bacillus thuringiensis* endotoxin" as endotoxins do not have codons, although the DNAs encoding them do.

Double Patenting

6. Claim 32 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,484,956 in view of Adang et al (US 5,380,831, filed September, 1988). The rejection is repeated for the reasons of record as set forth in the Office action mailed 20 December 2003. Applicant's arguments filed 30 March 2003 have been fully considered.

Applicant urges that a terminal disclaimer will be filed upon indication that the claims are otherwise allowable (response pg 11).

This is acknowledged.

7. Claims 11-19, 21-25 and 27-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-51 and 57-58 of Application No. 07/508,045, now U.S. Patent No. 5,484,956. The rejection is repeated for the

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reasons of record as set forth in the Office action mailed 20 December 2003 as applied to claims

11-31. Applicant's arguments filed 39 March 2003 have been fully considered.

Applicant urges that a terminal disclaimer will be filed upon indication that the claims are otherwise allowable (response pg 11).

This is acknowledged.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (571) 272-0547.

Anne R. Kubelik, Ph.D.
June 9, 2004



**ANNE KUBELIK
PATENT EXAMINER**